

## **Urgent Field Safety Notice**

---

**Commercial name/Model:** DA8K-10-14453 British standard power cord

**FSCA-identifier:** CP1905-JH00686

**Type of action:** Device exchange

---

June 2019

**Attention:** [Hospital/Distributor Name]

Dear Sir or Madam,

Through the continuous monitoring of the products distributed by Mindray, we have become aware of a potential issue may be associated with a batch of British standard power cord used on some of Mindray's products. This letter is intended to provide you with information as following:

### **Details on affected devices:**

The affected batch No. of the British standard power cord is 42/18 which can be identified from the label. How to identify the batch number is listed in **appendix 1**

### **Description of the problem:**

The affected British standard power cord may cause the earth leakage protection system of the hospital to trip.

To date, there are no reports of patient injuries associated with this potential issue.

### **Advise on action to be taken by the Hospital administrator:**

1. Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.
2. Please stop using the affected power cord according to the affected list. Your local Mindray Service Representative will contact you as soon as possible to replace the affected British standard power cord.

### **Advise on action to be taken by the distributor:**

1. Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been delivered.
2. If any products in your facility are on the affected list, please do not sell or install these devices to customers. Mindray Service Representative will contact you to replace the affected British standard power cord.

### **Transmission of this Field Safety Notice:**

This Notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

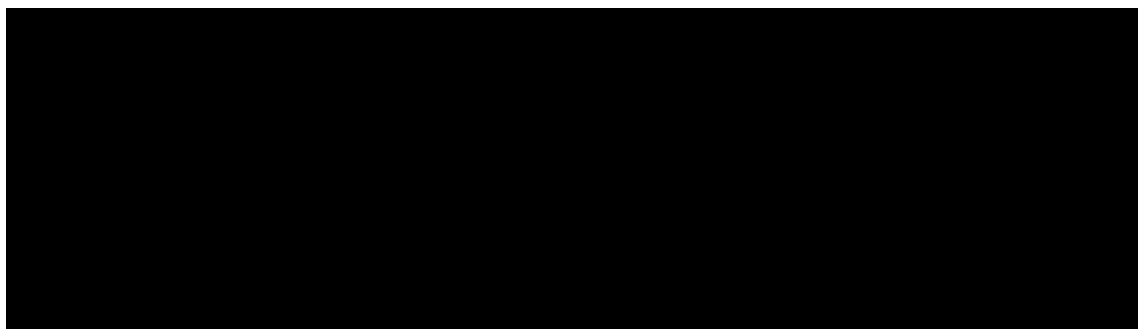
We would be grateful if you could confirm receipt of this letter. Please fill in below Acknowledgement Form and return via E-mail or Fax.

**Contact reference person:**

We apologize for the inconvenience caused by this situation. If you have any questions, please contact with your local Mindray Customer Service Engineer or designated Technical Support Engineer – Liu Angju

Organization: Shenzhen Mindray Bio-Medical Electronics Co., LTD  
Tel: 0086-755-81886680  
Fax: 0086-755-26582680  
Email: unicorn.ajiliu@mindray.com

This Notice has been notified the appropriate Regulatory Agency.



SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD  
Mindray building, Keji 12th Road South, High-tech Industrial Park, Nanshan,  
Shenzhen 518057, P.R.China  
Tel: 0086 755 8188 5479  
Fax : 0086 755 26582680  
Email : mr@mindray.com

Acknowledgement Form

=====  
**Confirmation of Receipt of Field Safety Notice**  
**Affected Products :** *DA8K-10-14453 British standard power cord*  
**FSCA :** *CP1905-JH00686*  
**Type of FSCA :** *Device exchange*  
=====

**Please fill in this form and return this confirmation by E-mail or Fax immediately.**

**Fax:** 0086-755-26582680  
**Email:** unicorn.ajiliu @mindray.com

Name: \_\_\_\_\_

Tel. No.: \_\_\_\_\_

E-mail address: \_\_\_\_\_

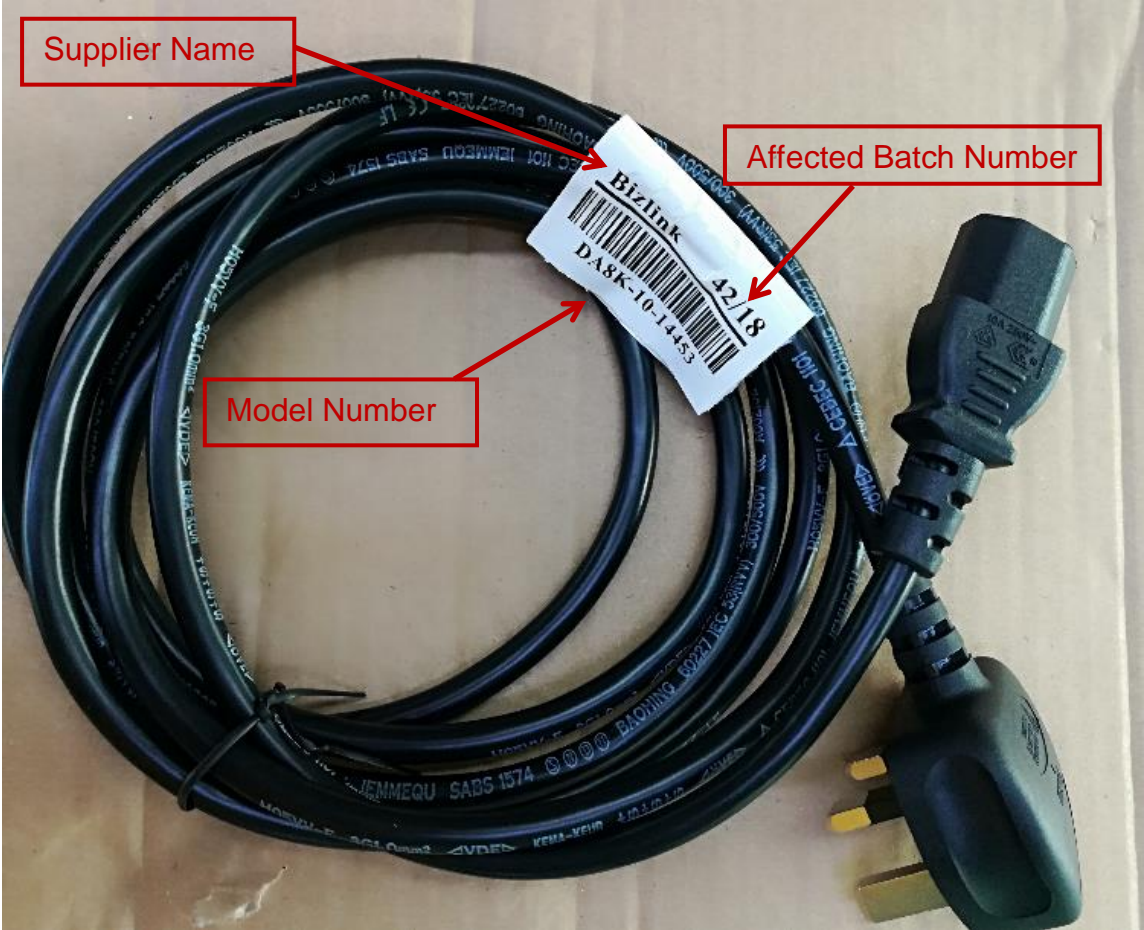
Date and Signature: \_\_\_\_\_

Address of the Organization:  
\_\_\_\_\_  
\_\_\_\_\_

**Appendix 1 List of Affected Devices**

The label attached to the power cord contains the supplier name , model number and the batch number. Please refer to below pictures:

**Figure 1 The information on the label**



**1. List of British standard power cord which distributed with equipments**

<b>Country</b>	<b>Equipment S/N</b>	<b>Commercial name/Model</b>	<b>British standard power cord quantity</b>	<b>Distributor/Hospital</b>	<b>Contact person</b>	<b>Address</b>	<b>Telephone</b>	<b>Email</b>